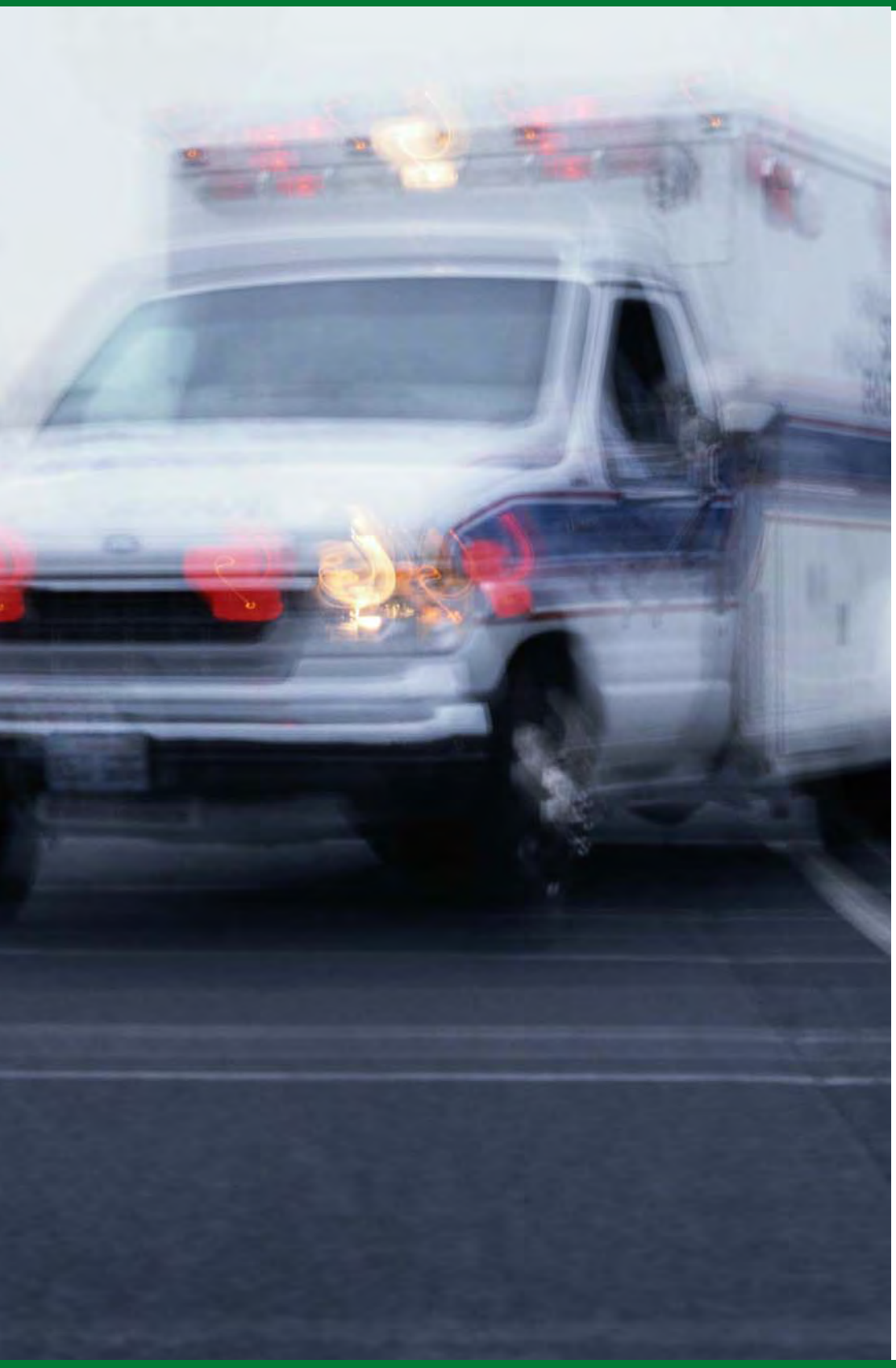


# H1N1 Clinic Immunization Training for Vaccinators

November 2009

VERMONT
DEPARTMENT OF HEALTH

# H1N1 Clinic Immunization Training For Vaccinators

## Table of Contents

# I. Overview of Manual

The Vermont Department of Health has organized vaccination clinics in response to the need to vaccinate Vermonters with the Influenza A (H1N1) 2009 Monovalent Vaccine. The initial goal of this campaign is to vaccinate as many Vermonters as possible in the target populations identified by the Centers for Disease Control and Prevention.

This manual has been created for clinicians to provide information and training about the Influenza A (H1N1) 2009 Monovalent Vaccine. It includes an overview of the vaccine, guidelines for administration, and an overview of medical management in the case of vaccine adverse events.

In addition, specific information related to a variety of questions about the safety of the vaccine has been added to facilitate answering questions.

## II. General Questions & Answers for Novel H1N1 Vaccine Safety

### H1N1 Influenza Vaccine Safety

**Will the 2009 H1N1 influenza vaccines be safe?**
We expect the 2009 H1N1 influenza vaccine to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects following flu vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and will work with state and local health officials to investigate any unusual events.

**Are there any side effects to the 2009 H1N1 influenza vaccine?**
CDC expects that any side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare. If side effects occur, they will likely be similar to those experienced following seasonal influenza vaccine. Mild problems that may be experienced include soreness, redness, or swelling where the shot was given, fainting (mainly adolescents), headache, muscle aches, fever, and nausea. If these problems occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot is given.

**Will the 2009 H1N1 vaccines that are currently recommended contain adjuvants (substances that enhance a patient's response to the vaccine)?**
No. According to current federal plans, only unadjuvanted vaccines will be used in the United States during the 2009 flu season. This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines will contain adjuvants.

2009 H1N1 vaccines with adjuvants are being studied to determine if they are safe and effective. Experts will review these data when they are available. There is no plan at this time to recommend a 2009 H1N1 influenza vaccine with an adjuvant.

**Will the 2009 H1N1 influenza vaccine contain thimerosal?**
The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some 2009 H1N1 influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal. For more information on thimerosal, go to www.cdc.gov/h1n1flu/vaccination/thimerosal_qa.htm

**Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine?**
Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Infection with the bacterium Campylobacter jejuni, which can cause diarrhea, is one of the most common risk factors for

GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. FDA and CDC will be closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines, including GBS.

## III. Vaccine Information for 2009 Novel H1N1 Vaccine: Summary

The U.S. Food and Drug Administration (FDA) approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, as well as the package inserts, visit FDA's website at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm

| Manufacturer | Presentation | Age | Dosage[1] | Type | Package Insert |
|---|---|---|---|---|---|
| CSL Limited | -0.5 mL pre-filled single-dose syringe (thimerosal free)<br>-5 mL multi-dose vial containing 10 doses (with thimerosal) | Adults 18 years of age or older | - Single 0.5 mL dose | Inactivated virus; intramuscular injection | link |
| GlaxoSmithKline[2] | *Awaiting FDA licensure* | | | | |
| Novartis Vaccines and Diagnostics Limited | - 0.5 mL pre-filled single-dose syringe (trace thimerosal)<br>- 5 mL multi-dose vial (with thimerosal) | Persons 4 years of age and older | -Two 0.5 mL doses approx. 1 month apart for children 4 to 9<br>-Single 0.5 mL dose for children 10-17<br>-Single 0.5 mL dose for adults 18 and older | Inactivated virus; intramuscular injection | link |
| Sanofi Pasteur Inc. | -0.25 mL pre-filled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod<br>-0.5 mL pre-filled single-dose syringe (thimerosal free)<br>- 0.5 mL single-dose vial (thimerosal free)<br>- 5 mL multi-dose vial (with thimerosal) | Persons 6 months and older | -Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age<br>-Two 0.5 mL doses approx. 1 month apart for children 36 months -9 years<br>-Single 0.5 mL dose for children 10 years and older<br>-Single 0.5 mL dose for adults 18 and older | Inactivated virus; intramuscular injection | link |
| MedImmune, LLC | -0.2 mL pre-filled single-dose intranasal sprayer | Persons aged 2 to 49 years | -Two 0.2 doses approx. 1 month apart for children 2 to 9<br>-Single 0.2 mL dose for persons 10-49 | LAIV; Intranasal spray | link |

[1] Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

[2] The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL pre-filled single-dose syringes (thimerosal free).

## IV. Vaccine Storage and Handling

Multi-dose vials that contain a bacteriostatic agent, usually thimerosal, can be used until the date of expiration once they are opened, unless the vial becomes visibly contaminated or it is not stored at the correct temperature. Label an open multi-dose vial with the date and time it was opened. Store vaccines separate from other medications and biologics. Do not store food or beverages in the same refrigerator or freezer as vaccines.

## V. General Guidelines for Vaccine Administration

### A. Administration Guidelines

Appropriate vaccine administration is critical to vaccine effectiveness. The recommended site, route and dosage for each vaccine are based on clinical trials, practical experience and theoretical considerations. The following information provides general guidelines for administration for those who administer the vaccines, as well as those in training, education and supervisory positions. This information should be used in conjunction with professional standards for medication administration, vaccine manufacturers' product guidelines, CDC's Advisory Committee on Immunization Practices (ACIP) General Recommendations on Immunization, the American Academy of Pediatrics' Report of the Committee on Infectious Diseases Red Book and state/agency-related policies and procedures.

**For school clinics:**

**Preparation of student:**

Students should be prepared for vaccination with consideration of their age and stage of development.

**Screening of students:** The screening of the student will be done before the day of clinic for any contraindications and precautions for the vaccine. If a consent form indicates that a student has a vaccine contraindication, the school nurse will follow up with the parents. The parents will be asked to obtain a prescription from the child's physician stating that the child may be vaccinated in the school setting. Adults vaccinated in the school setting will also need to obtain a prescription for vaccination if they have a contraindication.

**Vaccine Safety and Risk Communication**: Parents /guardians were given a Vaccine Information Statement (VIS), a letter about the vaccine and a consent form. Vaccinators should be knowledgeable about the vaccine they are administering and any contraindications to vaccination.

**Traumatic Care:** Vaccinators need to display confidence and establish an environment that promotes a sense of security and trust for the patient. Vaccinators need to use a variety of techniques to minimize the stress and fear of injections. One way the vaccinator can accommodate for the patient's comfort is positioning and restraint. For the younger child, a trusted adult can hold them during the administration of the vaccine.

**Pain Control:** Pain is subjective and varies with each individual. Diversionary techniques to provide distraction can be used that are age-appropriate and non-pharmacologic. Non-aspirin containing pain relievers can be used after the injection if prior permission is given by the parent/guardian. This can be left up to the school nurse who has the student's file.

**Infection Control:** Standard precautions should be followed during the administration of the vaccine. Wash hands using soap/water or alcohol-base waterless antiseptic before vaccine

preparation and each student/patient. Wearing gloves is not mandatory or expected when administering vaccines unless there is potential for exposure to blood and body fluids or the vaccinator has open hand lesions.

**For non-school clinics**

**Screening of patients:** The screening of the patient will be done before the patient reaches the EMS vaccinator. Any patient with a contraindication will need to obtain a prescription for vaccination.

**Vaccine Safety and Risk Communication**: Patients receive a Vaccine Information Statement (VIS) and a consent form. Vaccinators should be knowledgeable about the vaccine they are administering and any contraindications to vaccination.

**Traumatic Care:** Vaccinators need to display confidence and establish an environment that promotes a sense of security and trust for the patient. Vaccinators need to use a variety of techniques to minimize the stress and fear of injections. One way the vaccinator can accommodate for the patient's comfort is positioning and restraint. For the younger child, a trusted adult can hold them during the administration of the vaccine.

**Pain Control:** Pain is subjective and varies with each individual. Diversionary techniques to provide distraction can be used that are age-appropriate and non-pharmacologic.

**Infection Control:** Standard precautions should be followed during the administration of the vaccine. Wash hands using soap/water or alcohol-base waterless antiseptic before vaccine preparation and each student/patient. Wearing gloves is not mandatory or expected when administering vaccines unless there is potential for exposure to blood and body fluids or the vaccinator has open hand lesions.

Adapted from: VDH Clinical Procedure Manual

## B. Target Groups

The CDC's Advisory Committee on Immunization Practices (ACIP) has recommended the following groups as "target populations" for receiving the H1N1 vaccine. At the onset, only target populations will receive the vaccine. Additional populations will be considered as additional vaccine and guidance from the CDC becomes available.

- Pregnant women
- Household contacts of children less than 6 months of age
- Healthcare workers & EMS workers
- Persons 6 months through 24 years old
- Persons 25-64 years old with health conditions associated with higher risk of medical complications from influenza.

It is thought that enough vaccine will be available for every person in the target population (accounting for overlap in groups and anticipated acceptance rates). However the ACIP has also recommended that the following groups be identified as "priority groups". These groups would receive vaccine first if the supply was severely limited:

- Pregnant women
- Household contacts of children less than 6 months of age
- Healthcare workers & EMS workers
- Persons 6 months through 4 years old
- Persons 5-18 years old with health conditions associated with higher risk of medical complications from influenza.

## VI. Immunization Administration

**Note:** If you wish to watch a video demonstrating the administration of IM vaccine, contact the Health Department District Office and ask to borrow the Immunization Technique DVD.

### A. Prior to administering vaccine:

1. Review package insert and verify clinic's medical orders.
2. Observe client's right to confidentiality.
3. Have client discard any food or gum in their mouth.
4. Verify client's identity.
5. Identify yourself and explain the procedure to the client/parent/guardian.
6. Ensure that the VDH Immunization Consent Form is signed and that no contraindications to vaccination exist. This can be done by glancing quickly at the Consent Form, since the form will have been reviewed by a clinic worker (and by the school nurse in a school setting) before the recipient is allowed to proceed to the vaccinator.
    a. Only individuals with complete forms will be allowed to be vaccinated.
    b. If an individual has an identified contraindication to vaccination, the only way he or she will be vaccinated at a clinic is if the consent form has a prescription to vaccinate from the individual's health care provider attached.

### B. Drawing up Vaccine

Most vaccines come in **multi-dose** vials ready to draw up (or in prefilled syringes with or without needles).

1. Observe standard precautions.
2. Shake vial vigorously and check the fluid for color, cloudiness, and suspension and verify that it matches what is stated in the manufacturer's package insert.
3. If it doesn't look as it should, refer to the Immunization Manual - Vaccine Accountability for returning vaccine to the immunization program.
4. Get another vial and do the same checks as stated above.
5. Choose appropriate needle (see next page). The same needle used for drawing up the vaccine is used for giving the immunization. You only need to get a different syringe if the needle is damaged.
6. Wipe stopper of vial with an alcohol prep pad.
7. Pull syringe back to line marking the # cc to be given to fill with air.
8. Uncap the needle. (For pre-filled syringes, firmly attach needle into a Luer Lock syringe with a push and clockwise twist. Pull back on the safety cover toward the syringe and away from the needle. Grasp the syringe with one hand and with the other pull the clear needle shield straight off.)
9. Insert the needle into the stopper.
10. Insert the air into the vial to equalize pressure.
11. Invert the vial and withdraw the required dose (or appropriate amount) of vaccine.
12. With the needle pointing upward, check for air bubbles; gently tap the syringe so the large bubbles move to the top of the syringe.

13. Withdraw the needle.
14. Recap the needle (the needle has not been used on a client).
15. For large bubbles at the tip, expel them by tapping the syringe. Be careful you do not lose any vaccine.
16. For a multi-dose vial, ensure you draw up accurately so you get all the doses from the vial. This drawing up technique will allow you to get accurate doses.
17. Drawing up vaccine in preparation for mass immunization clinics:
    a. Vaccines should be drawn up as close to the time of administration as possible. Once the vaccine is drawn up, it should be placed in the refrigerator or in a container with cold packs.
    b. In situations where pre-filling syringes will occur:
        i. Vaccinators should draw up the vaccine that they will administer. If another vaccinator will draw the vaccine, the person administering the vaccine will validate contents of the syringe by observing the vial prior to the syringes being filled and by keeping the person who is drawing up the vaccine within sight throughout the syringe filling process.
        ii. Store syringes with vaccines of the same type and same lot number in separate or divided containers or trays.
        iii. Label each syringe.
        iv. Label each container of tray.
        v. Syringes other than those filled by the manufacturer must be discarded at the end of the day.
    c. To avoid wasting vaccine:
        i. Do not draw up more vaccine than will be used at the clinic or session. It is recommended that a vaccinator draw up no more than what will be used in 1-2 hours of clinic time.
        ii. Ensure the cold chain is maintained until the vaccine is administered.
        iii. Adhere to sterile technique when drawing up the vaccine. If a vaccinator is drawing up one dose of vaccine at a time, the stopper will be cleaned with an alcohol swab each time before a dose is drawn. If a vaccinator will pre-fill many syringes one after the other, the stopper only needs to be cleaned with an alcohol swab prior to the first draw.

## C. Intramuscular Injections

1. Two sites are recommended for IM vaccinations.
    a. For infants and toddlers, the vastus lateralis is the preferred site. This site can be found in the anterolateral thigh. Locate the knee and the greater trochanter of the femur. Visually divide the area between these two points into thirds, inject in the middle lateral third. Each client is different, therefore the limb needs to be exposed so you can visualize where the vaccine should be injected. Each vastus lateralis should be able to accommodate two IM injections.
    b. For children and adults, the deltoid is the preferred site. This site can be located approximately 3 fingers below the acromion process, above the level of the armpit. Each client is different, therefore the limb needs to be exposed so you can visualize where the vaccine should be injected. Each deltoid should be able to accommodate up to two IM injections.
    c. The buttock is **never** recommended because the muscle is thin and there is a risk of injecting into or near the sciatic nerve.

2. Needle Size:
    a. Choice of needle depends on the volume and the thickness of the vaccines to be administered as well as the thickness of tissue that needs to be penetrated. With most vaccines, the volume

of the dose is small and most are suspensions, so they are thin fluids, therefore you can usually use a 23 or 25 gauge needle. The higher the gauge, the thinner the needle.

b. For intramuscular injections to penetrate all the way through the SC tissue and to deposit the vaccine into the muscle, a 1" or longer needle should be used. Care must always be taken to deliver the vaccine deeply into the muscle.
c. Use a 1" needle even on tiny infants, 5/8" needle is not long enough for IM injections and should not be used.
d. For large or obese adults, 1 1/2" needle may be needed.

3. Injections:

a. Have recipient either stand or sit for vaccination. For younger children, it is helpful to have an adult help with comforting and holding the child.
b. Perform hand hygiene and put nonlatex gloves on if indicated.
c. Clean the skin in a 2" radius of the injection site with alcohol. Allow area to air dry.
d. Shake syringe, uncap the needle and grasp it like a dart.
e. Hold the needle 1" away from the injection site.
f. Using the non-dominant hand, compress the client's muscle between your fingers.
g. Quickly insert the needle at a 90-degree angle.
h. It is not necessary or recommended to pull back the plunger before depositing the vaccine. There are no major blood vessels in either of the recommended injection sites.
i. Inject vaccine with steady pressure on the plunger. Remove the needle.
j. Activate safety device. For non pre-filled syringes, you may need to apply more pressure on the plunger to activate the safety device. For pre-filled syringes, after removing the needle from the injection site, immediately activate the safety devices as follows: Using the same hand holding the syringe, center thumb or forefinger on the finger pad area of the safety cover. Push the cover forward over the needle until you hear and/or feel it lock. Visually confirm the needle tip is covered.
k. Immediately discard syringe into a sharps container.
l. Apply pressure with gauze. Use appropriate bandage, if needed.
m. Document vaccine administration.
n. Have client/parent/guardian remain on site for 15 minutes for observation.
o. Please see Section VII – Post Vaccination Adverse Events for guidance on managing an adverse event.

Adapted from the VDH Clinical Procedure Manual

## D. (LAIV) - FluMist™ Administration of Live Attenuated Influenza Vaccine

This section has been deleted from the EMS version of this training program because EMS personnel are not authorized to administer influenza vaccine by the nasal route.

# VII. Post-Vaccination Adverse Events

## A. Medical Management

**I. Goal:** To ensure that vaccinators working on behalf of the Vermont Department of Health are prepared to manage the most common vaccine reactions and emergencies consistent with current standards of practice.

**II. Objective:** ***Prevention is the primary objective***. If the EMS vaccinator encounters a medical emergency, the EMT-I-03 or EMT-P will follow the statewide EMS protocols.

**III. Procedure:**

**NOTE: The information below is what VDH provides to those administering vaccines. The EMS vaccinator who encounters a medical emergency should follow the statewide EMS protocols.**

**A. Preparation and Client Screening:**

1. To minimize adverse reactions, clients should be carefully screened for precautions and contraindications before vaccine is administered.
2. Have current emergency service phone numbers posted next to each phone.
3. Know how to access local emergency medical services (EMS), and have clear directions to exact clinic location.
4. Have a First Aid Kit/Emergency box, epinephrine and a copy of Emergency Guidelines immediately available. All staff should know the location of these supplies.
5. It is recommended that all clinics have a trained CPR provider available while providing vaccinations.

**B. Fainting (syncope)**

**Symptoms**

Feels he/she is going to faint
Complains of lightheadedness, dizziness, restlessness
Skin is cool and clammy, sweating, pallor
Nausea
Ringing in ears, visual disturbances
Altered consciousness or loss of consciousness (usually brief, transient)
Self limited in supine position

**Vital Signs**

Pulse may be slow and weak (60 or less)
Blood pressure may be low or normal

**Management**

If fear is expressed before injection is given, have client sit or lie down for the injection.
If symptoms of syncope develop, assist client to supine position or Trendelenberg position (flat on back with feet elevated on chair) immediately.
Check for injuries if client has fallen.
Stay with the client to protect from injury. Reassure and calm the client's anxiety.
Put cold cloth to head. Give symptomatic relief (loosen clothing, keep crowds away).
If mild episode and client is sitting in a chair, try lowering head over knees and protect

client from falling. If no response, transfer to supine position.
Client should recover spontaneously. When alert, offer water or juice. Advise client to have a friend or family member accompany him/her home.
Do not use an ammonia inhalant due to potential respiratory or allergic reaction.
Monitor vital signs; make sure client is asymptomatic before standing.
If recovery is not prompt, call for help and activate EMS/call 911.

**C. Hyperventilation Syndrome**

**Symptoms:**

Lightheadedness, fatigue, weakness
Anxiety, panic
Numbness/tingling of hands, feet, and/or around the mouth
Rapid breathing, sighing
May end in fainting

**Management:**

Provide reassurance and calm the client's anxiety.
Counsel/coach slow breathing through nose.
Do not have person breathe into a paper bag.
If recovery is not prompt activate EMS/call 911.
See Syncope (fainting)

**D. Localized/minor reaction**

**Symptoms:**

Reaction at or around **injection site**
Itching, swelling, redness, increased warmth to site
Runny nose, watery eyes

**Management:**

Provide calm environment and supportive reassuring manner.
Apply cold compress or ice to injection site.
Refer client to primary care provider for anti-pruritic for itching or analgesic for pain, and to report sensitivity.

**E. Seizure**

**Symptoms:**

Client may be unconscious or have transient awareness of surroundings.
Client may be incontinent of urine or feces.
Rhythmic movements of limb(s), jaw, and/or eyeballs may be present.
Pulse is generally above 60

**Management:**

Assure client does not hurt himself/herself by falling. Try to lay client on floor if possible. Do not forcefully restrain. Remove objects that might injure client.
**Do not put anything into the client's mouth.**
Seizures are self-limited. If client still appears to seize after a few minutes call 911.
Following seizure, client may remain unconscious, be confused, or appear partially paralyzed.
Place client on side (recovery position) and watch for vomiting. Keep client in recovery position

until alert or emergency personnel (if called ) arrive.
Monitor VS until client is stable.
Reassure and support client.
Record incident/time/length of seizure/VS.
Advise transport home via friend/family.
Ensure the clinic advises the Immunization Program at VDH and completes VAERS Report (Vaccine Adverse Event Report).

**F. Anaphylaxis (rare) & Shock(extremely rare)**

**Symptoms:**

Sudden or gradual onset after injection of the following :

- itching of head, eyes, ear, throat, stinging/burning skin
- generalized urticaria (hives), erythema, and extreme itching
- anxiety, confusion, restlessness
- sneezing, coughing, headache
- angioedema (swelling of the lips, face, or throat)
- severe bronchospasm (wheezing), tightness in chest, difficulty breathing **visible swelling of throat and tongue, laryngeal or pharyngeal edema, stridor, loss of voice**
- Shortness of breath
- Nausea, vomiting, abdominal cramps
- Cold, clammy, sweaty, pale skin, cyanosis
- Dizziness, lethargy, syncope
- Altered or loss of consciousness
- Cardiovascular collapse, shock

**Vital Signs:**

- Pulse present and fast ($\geq$100) or thready or non-palpable
- Blood pressure less than 80 systolic

**Management:**

Call for help.

**Assess airway,** (if breathing is difficult, elevate head) if vomiting , place client on side to maintain open airway

Stay with the client. A second person should bring epinephrine & activate EMS/ call 911 immediately.

Place client in Trendelenburg position with feet above heart level. Rest legs on support so they are slightly higher than heart, loosen clothing.

**Administer epinephrine immediately for any respiratory involvement including swelling to face, neck, throat, wheezing with or without hives, and erythema and urticaria** (see medical orders).

**NOTE: An EMT-I-03 who determines epinephrine is indicated must contact on-line medical direction for authorization prior to administering epinephrine.**

Monitor the patient closely/ maintain open airway, until EMS arrives

Monitor BP and pulse q 3 to 5 minutes

If EMS has not arrived and symptoms are still present, repeat same dose of epinephrine every 10 to 20 minutes for up to 2 doses depending on client's response.

Prepare for transfer to Emergency Department via EMS.

Observe for cardiopulmonary arrest (no pulse and no breathing).

Perform CPR and continue until EMS arrives.
Record all VS, medications administered (time, dose, response and name of person who administered).
If EMS takes client to the hospital, give any used Epi-pens to the EMS worker.
Notify client's primary care provider.
Ensure the clinic advises the Immunization Program at VDH and completes VAERS Report (Vaccine Adverse Event Report).

Adapted from VDH Clinical Procedure Manual

## B. Epinephrine Dosage for Anaphylaxis and Shock

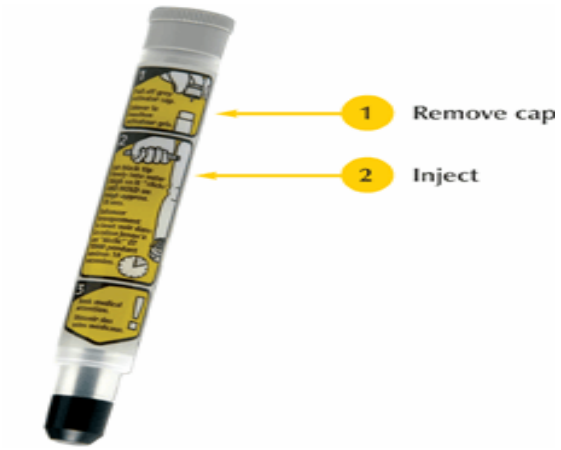
- Specific dosage guidelines will be contained in the VDH epinephrine medical orders.

## C. How to Use an Epi-Pen

1. Using an Epi-Pen correctly starts with holding the device correctly. The Epi-Pen should be held in a closed fist with the thumb folded over the fingers, and not placed over the end of the device.

2. Remove the yellow or green cap from the storage tube. Grasp the Auto-Injector with the black tip pointing down.

3. Place black tip against mid-outer thigh and press firmly until the Auto-Injector activates. Hold while counting for 10 seconds, then remove.



## D. Post-Vaccination Adverse Events Reporting Requirements

Any post-vaccination adverse event(s) **must** be reported to the Vaccine Adverse Event Reporting System (VAERS). The appropriate VAERS form and contact information should be readily available. Report all clinically significant events to the Vaccine Adverse Event Reporting System, regardless of whether or not you believe the events are caused by the vaccine. Providers can now submit VAERS reports via the INTERNET at: www.vaers.org.

In addition, report any post-vaccination adverse event to the patient's primary care provider. Also, encourage patients or their parents/legal representatives to report any post-vaccination adverse event that occurs after they leave your facility to their primary care provider

Provide the patient's primary care provider with a record of the relevant information about the immunization(s) given, including any adverse events. Encourage patients or parents/guardians to inform their primary care provider of any adverse event(s) following immunization after they leave your facility.

# VIII. APPENDIX

Centers for Disease Control and Prevention
Your Online Source for Credible Health Information

General Questions and Answers on Thimerosal

September 14, 2009, 11:00 PM ET

**What is thimerosal?**
Thimerosal is a mercury-based preservative that has been used for decades in the United States in multi-dose vials (vials containing more than one dose) of some vaccines to prevent the growth of microorganisms, such as bacteria and fungi, which may contaminate them.

**What are preservatives and why are they used in vaccines?**
In vaccines, preservatives are used to prevent the growth of bacteria and fungi in the event that they get into the vaccine. This may occur when a syringe needle enters a vial as a vaccine is being prepared for administration. Contamination by germs in a vaccine could cause serious illness or death. In some vaccines, preservatives are added during the manufacturing process to prevent microbial growth.

**Will the 2009 H1N1 influenza vaccine contain thimerosal?**
The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some vaccine manufacturers will be producing 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

**I have concerns about the use of thimerosal. Is thimerosal still being used?**
People have a right to expect the vaccines they receive are safe and effective. CDC and FDA also hold vaccines to the highest standards of safety. That is why CDC and FDA continually evaluate new scientific information about the safety of vaccines. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine. This was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems. The most recent and rigorous scientific research does not support the hypothesis that thimerosal-containing vaccines are harmful.

Thimerosal is an important preservative that protects vaccines against potential microbial contamination, which may occur in opened multi-dose vials of vaccine. Such contamination could cause serious illness or death. Since seasonal influenza vaccine is produced in large quantities for annual immunization campaigns, some of the vaccine is produced in multi-dose vials, and contains

thimerosal to safeguard against possible contamination of the vial once it is opened.

Three leading federal agencies (CDC, FDA, and NIH) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent organizations [The National Academy of Sciences' Institute of Medicine, Advisory Committee on Immunization Practices (ACIP), and the American Academy of Pediatrics (AAP)] reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines.

**Is thimerosal safe when used as a preservative in vaccines?**
CDC places a high priority on vaccine safety, surveillance, and research. CDC is aware that the presence of the preservative thimerosal in vaccines and suggestions of a relationship to autism has raised concerns. These concerns make the decisions surrounding vaccinations confusing and difficult for some people, especially parents. Numerous studies have found no association between thimerosal exposure and autism. Since 2001, no new vaccine licensed by FDA for use in children has contained thimerosal as a preservative and all vaccines routinely recommended by CDC for children under six years of age have been thimerosal-free, or contain only trace amounts, except for some formulations of influenza vaccine. Unfortunately, we have not seen reductions in the numbers of children identified with autism indicating that the cause of autism is not related to a single exposure such as thimerosal.

The federal government is committed to assuring the safety of vaccines. This is achieved by FDA oversight of rigorous pre-licensure trials and post-licensure monitoring by CDC and FDA. This commitment not only stems from our scientific and medical dedication, it is also personal – for most of us who work at CDC are also parents and grandparents. We too, place tremendous value on the health and safety of children.

*Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA*
*800-CDC- INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day - cdcinfo@cdc.gov*
A-Z Index

National Institute of
Neurological Disorders and Stroke
National Institutes of Health
Reducing the burden of neurological disease...

# Guillain-Barré Syndrome Fact Sheet

***What is Guillain-Barré syndrome?***

Guillain-Barré syndrome is a disorder in which the body's immune system attacks part of the peripheral nervous system. The first symptoms of this disorder include varying degrees of weakness or tingling sensations in the legs. In many instances the weakness and abnormal sensations spread to the arms and upper body. These symptoms can increase in intensity until certain muscles cannot be used at all and, when severe, the patient is almost totally paralyzed. In these cases the disorder is life threatening - potentially interfering with breathing and, at times, with blood pressure or heart rate - and is considered a medical emergency. Such a patient is often put on a respirator to assist with breathing and is watched closely for problems such as an abnormal heart beat, infections, blood clots, and high or low blood pressure. Most patients, however, recover from even the most severe cases of Guillain-Barré syndrome, although some continue to have a certain degree of weakness.

Guillain-Barré syndrome can affect anybody. It can strike at any age and both sexes are equally prone to the disorder. The syndrome is rare, however, afflicting only about one person in 100,000. Usually Guillain-Barré occurs a few days or weeks after the patient has had symptoms of a respiratory or gastrointestinal viral infection. Occasionally surgery or vaccinations will trigger the syndrome.

After the first clinical manifestations of the disease, the symptoms can progress over the course of hours, days, or weeks. Most people reach the stage of greatest weakness within the first 2 weeks after symptoms appear, and by the third week of the illness 90 percent of all patients are at their weakest.

***What causes Guillain-Barré syndrome?***

No one yet knows why Guillain-Barré—which is not contagious—strikes some people and not others. Nor does anyone know exactly what sets the disease in motion.

What scientists do know is that the body's immune system begins to attack the body itself, causing what is known as an autoimmune disease. Usually the cells of the immune system attack only foreign material and invading organisms. In Guillain-Barré syndrome, however, the immune system starts to destroy the myelin sheath that surrounds the axons of many peripheral nerves, or even the axons themselves (axons are long, thin extensions of the nerve cells; they carry nerve signals). The myelin sheath surrounding the axon speeds up the transmission of nerve signals and allows the transmission of signals over long distances.

In diseases in which the peripheral nerves' myelin sheaths are injured or degraded, the nerves cannot transmit signals efficiently. That is why the muscles begin to lose their ability to respond to the brain's commands, commands that must be carried through the nerve network. The brain also receives fewer sensory signals from the rest of the body, resulting in an inability to feel textures, heat, pain, and other sensations. Alternately, the brain may receive inappropriate signals that result in tingling, "crawling-skin," or painful sensations. Because the signals to and from the arms and legs must travel the longest distances they are most vulnerable to interruption. Therefore, muscle weakness and tingling sensations usually first appear in the hands and feet and progress upwards.

When Guillain-Barré is preceded by a viral or bacterial infection, it is possible that the virus has changed the nature of cells in the nervous system so that the immune system treats them as foreign cells. It is also possible that the virus makes the immune system itself less discriminating about what cells it recognizes as its own, allowing some of the immune cells, such as certain kinds of lymphocytes and macrophages, to attack the myelin. Sensitized T lymphocytes cooperate with B lymphocytes to produce antibodies against components of the myelin sheath and may contribute to destruction of the myelin. Scientists are investigating these and other possibilities to find why the immune system goes awry in Guillain-Barré syndrome and other autoimmune diseases. The cause and course of Guillain-Barré syndrome is an active area of neurological investigation, incorporating the cooperative efforts of neurological scientists, immunologists, and virologists.

***How is Guillain-Barré syndrome diagnosed?***

Guillain-Barré is called a syndrome rather than a disease because it is not clear that a specific disease-causing agent is involved. A syndrome is a medical condition characterized by a collection of symptoms (what the patient feels) and signs (what a doctor can observe or measure). The signs and symptoms of the syndrome can be quite varied, so doctors may, on rare occasions, find it difficult to diagnose Guillain-Barré in its earliest stages.

Several disorders have symptoms similar to those found in Guillain-Barré, so doctors examine and question patients carefully before making a diagnosis. Collectively, the signs and symptoms form a certain pattern that helps doctors differentiate Guillain-Barré from other disorders. For example, physicians will note whether the symptoms appear on both sides of the body (most common in Guillain-Barré) and the quickness with which the symptoms appear (in other disorders, muscle weakness may progress over months rather than days or weeks). In Guillain-Barré, reflexes such as knee jerks are usually lost. Because the signals traveling along the nerve are slower, a nerve conduction velocity (NCV) test can give a doctor clues to aid the diagnosis. In Guillain-Barré patients, the cerebrospinal fluid that bathes the spinal cord and brain contains more protein than usual. Therefore a physician may decide to perform a spinal tap, a procedure in which the doctor inserts a needle into the patient's lower back to draw cerebrospinal fluid from the spinal column.

***How is Guillain-Barré treated?***

There is no known cure for Guillain-Barré syndrome. However, there are therapies that lessen the severity of the illness and accelerate the recovery in most patients. There are also a number of ways to treat the complications of the disease.

Currently, plasma exchange (sometimes called plasmapheresis) and high-dose immunoglobulin therapy are used. Both of them are equally effective, but immunoglobulin is easier to administer. Plasma exchange is a method by which whole blood is removed from the body and processed so that the red and white blood cells are separated from the plasma, or liquid portion of the blood. The blood cells are then returned o the patient without the plasma, which the body quickly replaces. Scientists still don't know exactly why plasma exchange works, but the technique seems to reduce the severity and duration of the Guillain-Barré episode. This may be because the plasma portion of the blood contains elements of the immune system that may be toxic to the myelin.

In high-dose immunoglobulin therapy, doctors give intravenous injections of the proteins that, in small quantities, the immune system uses naturally to attack invading organisms. Investigators have found that giving high doses of these immunoglobulins, derived from a pool of thousands of normal donors, to Guillain-Barré patients can lessen the immune attack on the nervous system. Investigators don't know why or how this works, although several hypotheses have been proposed. The use of steroid hormones has also been tried as a way to reduce the severity of Guillain-Barré, but controlled clinical trials have demonstrated that this treatment not only is not effective but may even have a deleterious effect on the disease.

The most critical part of the treatment for this syndrome consists of keeping the patient's body functioning during recovery of the nervous system. This can sometimes require placing the patient on a respirator, a heart monitor, or other machines that assist body function. The need for this sophisticated machinery is one reason why Guillain-Barré syndrome patients are usually treated in hospitals, often in an intensive care ward. In the hospital, doctors can also look for and treat the many problems that can afflict any paralyzed patient - complications such as pneumonia or bed sores.

Often, even before recovery begins, caregivers may be instructed to manually move the patient's limbs to help keep the muscles flexible and strong. Later, as the patient begins to recover limb control, physical therapy begins. Carefully planned clinical trials of new and experimental therapies are the key to improving the treatment of patients with Guillain-Barré syndrome. Such clinical trials begin with the research of basic and clinical scientists who, working with clinicians, identify new approaches to treating patients with the disease.

***What is the long-term outlook for those with Guillain-Barré syndrome?***

Guillain-Barré syndrome can be a devastating disorder because of its sudden and unexpected onset. In addition, recovery is not necessarily quick. As noted above, patients usually reach the point of greatest weakness or paralysis days or weeks after the first symptoms occur. Symptoms then stabilize at this level for a period of days, weeks, or, sometimes, months. The recovery period may be as little as a few weeks or as long as a few years. About 30 percent of those with Guillain-Barré still have a residual weakness after 3 years. About 3 percent may suffer a relapse of muscle weakness and tingling sensations many years after the initial attack.

Guillain-Barré syndrome patients face not only physical difficulties, but emotionally painful periods as well. It is often extremely difficult for patients to adjust to sudden paralysis and dependence on others for help with routine daily activities. Patients sometimes need psychological counseling to help them adapt.

***What research is being done?***

Scientists are concentrating on finding new treatments and refining existing ones. Scientists are also looking at the workings of the immune system to find which cells are responsible for beginning and carrying out the attack on the nervous system. The fact that so many cases of Guillain-Barré begin after a viral or bacterial infection suggests that certain characteristics of some viruses and bacteria may activate the immune system inappropriately. Investigators are searching for those characteristic peptides in viruses and bacteria may be the same as those found in myelin, and the generation of antibodies to neutralize the invading viruses or bacteria could trigger the attack on the myelin sheath. As noted previously, neurological scientists, immunologists, virologists, and pharmacologists are all working collaboratively to learn how to prevent this disorder and to make better therapies available when it strikes.

**Where can I get more information?**

For more information on neurological disorders or research programs funded by the National Institute of Neurological Disorders and Stroke, contact the Institute's Brain Resources and Information Network (BRAIN) at:

BRAIN
P.O. Box 5801
Bethesda, MD 20824
(800) 352-9424
http://www.ninds.nih.gov

s. Certain proteins

"Guillian-Barré Syndrome Fact Sheet, NINDS. NIH Publication No. 05-2902

Prepared by the Office of Communications and Public Liaison, Bethesda, MD 09/15/2009

# VACCINE ADVERSE EVENT REPORTING SYSTEM

***IMPORTANT INFORMATION ABOUT VAERS***

As a healthcare provider, you can help monitor the safety of vaccines by promptly and accurately reporting any clinically significant adverse event that occurs following vaccination to the Vaccine Adverse Event Reporting System (VAERS). Clinically significant adverse events are those events that are of concern to you or your vaccinated patients or their caregivers. **Please report clinically significant adverse events after vaccination, whether or not you administered the vaccine and even if you are not sure if the vaccine caused the adverse event.**

VAERS is a US vaccine safety surveillance system, co-managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS is the front-line monitoring system for collecting and analyzing voluntary reports of adverse events following vaccination. CDC and FDA analyze VAERS reports to identify potential vaccine safety concerns that may need further study or public health action.

There are three ways to report to VAERS:
1) Submit online via a secure website at https://secure.vaers.org/VaersDataEntryintro.htm
2) Fax a completed VAERS form to 877-721-0366, or
3) Mail a completed VAERS form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

A VAERS form may be downloaded from the VAERS website at www.vaers.hhs.gov/pdf/vaers_form.pdf. Alternatively, you may request a VAERS form by sending an email to info@vaers.org, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366.
For additional information on VAERS or vaccine safety, visit the VAERS website at www.vaers.hhs.gov or call 800-822-7967.

When submitting a report to VAERS, please include as much information requested on the form as possible to assist VAERS staff who analyze and follow-up on the adverse event. For example, please include information about vaccination location, date, vaccine type, lot number and dose. The form also includes a space to provide contact information for the person reporting the adverse event.

Influenza vaccination record cards http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/h1n1vaxrecord.pdf will be given to people who receive 2009 influenza A (H1N1) monovalent vaccine. The information on this card may be helpful in completing a VAERS report for an adverse event that occurred after 2009 H1N1 or seasonal influenza vaccines.

Thank you in advance for your support of our nation's immunization programs. Together we can ensure that vaccination continues to be as safe as possible.

WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

# VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
**PATIENT IDENTITY KEPT CONFIDENTIAL**

***For CDC/FDA Use Only***
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy Time _____ AM PM

11. Adverse event onset mm dd yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

| | Vaccine (type) | Manufacturer | Lot number | Route/Site | No. Previous Doses |
|---|---|---|---|---|---|
| a. | | | | | |
| b. | | | | | |
| c. | | | | | |
| d. | | | | | |

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

| | Vaccine (type) | Manufacturer | Lot number | Route/Site | No. Previous doses | Date given |
|---|---|---|---|---|---|---|
| a. | | | | | | |
| b. | | | | | | |

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

21. Adverse event following prior vaccination (check all applicable, specify)

| | Adverse Event | Onset Age | Type Vaccine | Dose no. in series |
|---|---|---|---|---|
| ☐ In patient | | | | |
| ☐ In brother or sister | | | | |
| | | | | |

***Only for children 5 and under***

22. Birth weight _____ lb. _____ oz.

23. No. of brothers and sisters

***Only for reports submitted by manufacturer/immunization project***

24. Mfr./Imm. proj. report no.

25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No

27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

**BUSINESS REPLY MAIL**
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

*POSTAGE WILL BE PAID BY ADDRESSEE*

**VAERS**
P.O. Box 1100
Rockville MD 20849-1100

## DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

### GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

### SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10: and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.